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10/569,958	11/03/2006	Kristine Fuimaono	32860-001018/US	3084
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HARNESS, DICKEY & PIERCE, P.L.C.			NGUYEN, HIEN NGOC	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/569,958	Applicant(s) FUIMAONO ET AL.	
	Examiner HIEN NGUYEN	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/22/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment to claims 13 and 14 is acknowledged and has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 12, 14, 22-24, 1-3, 5, 8-9 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Packer et al. (US 6,556,695).

Regarding claims 12, 14 and 22-24 Packer discloses:

- at least one input interface for electroanatomical 3D mapping data and 3D image data; (see Fig. 1, col. 2, lines 14-60, col. 3, lines 51-67). Packer discloses a system that perform an imaging method therefore the system must have at least one input interface for electroanatomical 3D mapping data and 3D image data.
- a segmentation module constructed for segmenting the 3D image data in order to extract a 3D surface profile of objects contained within a volume

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record by way of the 3D image data; (see Fig. 2A, col. 6, lines 14-45 and col.7, lines 7-23).

- a registration module connected to the segmentation module constructed for an automatic correlation with the correct position and dimension of the electroanatomical 3D mapping data and the 3D image data representing the 3D surface profile, by surface matching of the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data in at least one stage of the registration; (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36).
- a visualization module connected to the registration module to superimpose the 3D mapping data and at least the 3D image data representing the 3D surface profile on one another in the correct position with the correct dimension and provide these for visualization via a display device; (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36).
- visualization module is constructed for real time visualization of a part of a catheter that is used within a representation of the 3D image data that forms at least the 3D surface profile; (see col. 2, line 14-60 and col. 13, lines 1-23).
- the 3D image data of the area to be treated are recorded with at least one of X-ray computer tomography and magnetic resonance tomography; (see col. 1, lines 15-35 and col. 3, lines 51-67).

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- the 3D image data of the area to be treated are recorded using 3D ultrasound; (see col. 1, lines 15-35 and col. 3, lines 51-67).
- Regarding claim 1, this method is performed by a device in claim 12.

Therefore the method is rejected for the same reason as in claim 12. The 3D image data of the area to be treated is recorded with tomographical 3D imaging before the catheter application is carried out because the purpose of recording 3D image data is to help guide the catheter during the medical procedure. The system recorded 3D tomographical image data to help guide the catheter inside the patient body (see col. 1, lines 15-35 and col. 3, lines 51-67).

Regarding claim 2, this method is performed by a device in claim 23, therefore the method is rejected for the same reasons stated in the rejection of claim 23.

Regarding claim 3, this method is performed by a device in claim 24, therefore the method is rejected for the same reason as in claim 24.

Regarding claim 5, Packer discloses:

- the 3D image data are visualized via a volume rendering technique; (see col. 6, line 1-13).

Regarding claim 8, this method is performed by a device in claim 14. Therefore the method is rejected for the same reason as in claim 14.

Regarding claim 9, Packer discloses:

- visualize catheter without superimposition of the 3D mapping data from time to time; (see col. 2, lines 53-60).

Regarding claim 19, this method is performed by a device in claim 22.

Therefore the method is rejected for the same reason as in claim 22.

Regarding claim 20, this method is performed by a device in claim 23.

Therefore the method is rejected for the same reason as in claim 23.

Regarding claim 21, this method is performed by a device in claim 24.

Therefore the method is rejected for the same reason as in claim 24.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 13, 18 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Hemler et al. (A System for Multimodality Image Fusion (provided as prior art in the IDS)) and further in view of Williams et al. (DE 19953308-A1 (provided as prior art in the IDS)).

Regarding claim 13, Packer discloses substantially all claim limitation set forth in claim 12 above. However, he does not disclose correlate the correct

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position and the correct dimension using distinct anatomical points and artificial marker.

Hemler discloses:

- correlate the correct position and the correct dimension using distinct anatomical points as an effective way to ensure the images on display are in correct position and dimension; (see page 337, line 7- page 338, line 32).

Williams discloses:

- correlate the correct position and the correct dimension using artificial marker as an effective way to ensure the images on display are in correct position and dimension; (see abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's system to correlate the correct position and the correct dimension using distinct anatomical points and artificial marker taught by Hemler and Williams because using distinct anatomical points and artificial marker are effective way to ensure the images display are in correct position and dimension.

Regarding claim 18, Packer discloses:

- visualization module is constructed for visualizing a part of a catheter used within a representation of the 3D image data, forming at least the 3D surface profile, in real time; (see col. 2, line 14-60).

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Regarding claim 4, the method is performed by a device in claim 13. Therefore the method is rejected for the same reason as in claim 13.

5. Claims 15-16, 10-11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695) and in view of Solomon et al. (US 2003/0018251)

Regarding claims 15 and 16, Packer discloses substantially all claim limitation set forth in claim 14. However, he does not disclose a calculation module to calculate an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data, the visualization module being constructed for the coded representation of the calculated distance in real time.

Solomon discloses:

- a system that included a calculation module to calculate an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data, the visualization module being constructed for the coded representation of the calculated distance in real time for better visualization for the operator; (see [0056], [0057] and [0058]). The calculation module is inside the system. The system has to have a calculation module in order to make the calculation.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's system with a calculation module to calculate an instantaneous distance of a catheter tip from a predeterminable picture element

of the 3D image data, the visualization module being constructed for the coded representation of the calculated distance in real time taught by Solomon because the coded representation provide a better visualization for the operator and the operator can easily determine the distance by looking at the color code.

Regarding claim 10, this method is perform by a device in claim 15.
Therefore the method is rejected for the same reason as in claim 15.

Regarding claim 11, this method is perform by a device in claim 16.
Therefore the method is rejected for the same reason as in claim 16.

Regarding claim 17, this method is perform by a device in claim 15.
Therefore the method is rejected for the same reason as in claim 15.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695) and in view of Massaro et al. (2002/0087329).

Packer does not disclose visualized image data on a polygonal grid.
Massaro discloses:

- visualize image on a polygonal grid for easily matching location and distance; (see claim 58).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's method to visualized image data on a polygonal grid taught by Massaro because with a polygonal grid the viewer can easily match location and determine distance.

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7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Shoji et al. (US 6,572,476) and further in view of Chiu et al. (US 2004/0233217).

Packer does not disclose adjustable transparency and adjustable blending factor.

Shoji discloses:

- adjustable transparency to make the image more or less visible; (see col. 9, lines 1-22).

Chiu discloses:

- adjustable blending factor to control the visibility of the output image; (see [0007-0008]).

It would have been obvious to one of ordinary skill in the art to modify Packer's method with adjustable transparency and adjustable blending factor taught by Shoji and Chiu because adjustable transparency and adjustable blending factor allow the operator to adjust the level of visibility of the images.

Response to Arguments

Applicant's arguments filed 02/19/2009 have been fully considered but they are not persuasive. Regarding claims 1 and 12 applicant argued that Parker fails to disclose an automatic correlation with the correct position and dimension of the electroanatomical 3D mapping data and the 3D image data by surface matching. Further, Applicant argued that Parker's registration and matching process is a manual

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process (applicant argument page 12, lines 1-6). The examiner disagree, applicant argument on page 12, lines 1-6 is directed to a manual process of producing an electrical map and not a process of register and merge/superimpose mapping data and image data upon one another and automatically correlate position and dimension using matching technique. Examiner interprets the limitation of claims 1 and 12 as register and superimpose mapping data and image data upon one another and automatically correlate position and dimension using matching technique and this is disclosed by Parker (col. 2, lines 14-60, col. 9, line 21-col. 10, line 36 and Fig. 1, the high resolution image register with the real time image using matching technique; this is the same as register, superimpose and match mapping data with image data; high resolution image contain electrical activation map which is the mapping data). Automatically produce electrical map is not recited in the claim. Further, It would be inherent that register, superimpose and matching technique is automated by the system because this requires transformation and calculation of image and coordinate and it is not possible to perform this task by hand and produce a real-time image. Parker's system produce real-time image therefore it requires very fast calculation by using computer processor.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEN NGUYEN whose telephone number is (571)270-7031. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3768

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768